

In accordance with the claims objection, the present claims assign letters to the method steps, instead of numbers.

Reconsideration is requested with respect to the rejection of claims 1, 4, and 6 under 35 USC 112, ¶2, for a allegedly being indefinite. Reconsideration is requested in view of the changes to the claims effected, hereby, taken in conjunction with the following remarks.

The statement of rejection raises issues 3a - 3f (Office Action pages 2-4) in connection with the rejected claims. In response to item 3a, "analyzing the PaSS and/or genome semi-distance(s) which was/were obtained in step 4" is changed, hereby, to read

comparing the PaSS and/or genome semi-distance(s) which was/were obtained in step d) to PaSS and/or genome semi-distance(s) recorded in a database to identify the organism,
wherein the PaSS and/or genome semi-distance(s) recorded in the database is obtained by a method in which steps a) to d) are carried out with respect to known organisms under the same conditions as the steps a) to d) carried out on the organism to be identified.

The comparison procedures are disclosed on page 22, line 5 from the bottom to page 23, line 23, of the specification as filed.

In response to item 3b, "kind" is deleted.

In response to item 3c, "extracting identification dots of each DNA fragment from an electrophoretic pattern which was obtained in step 2" is changed, hereby, to read "identifying featuring points of each DNA fragment from an electrophoretic pattern which was obtained in step b)," as suggested in the statement of rejection. Applicants wish to thank the Examiner for kindly suggesting alternative claim language for overcoming the rejection.

In response to item items 3d(1) and 3d(2), the end of claim 1 is amended, hereby (in claim 8), to read

wherein in the electrophoresis by TGGE or DGGE, a standard DNA is co-migrated with the double-stranded DNA fragments as an internal reference for providing a standard point and location of the recorded position of the featuring points is determined in relation to the featuring points of the standard DNA.

By this amendment, the meaning of the phrase "a standard DNA is co-existed as a standard point for the identification dots and the pseudo-absolute location of the recorded position of the featuring points identification dots is determined" is clarified.

In response to item 3e, "raw material" in claim 4 is changed to read "material" in claim 11.

In response to item 3f, the abbreviation "PaSS" is spelled out "Pattern Similarity Score," in present claim 8, from which claims 11 and 12 (corresponding to rejected claims 4 and 5, respectively) depend. In connection with item 3f, the statement of rejection maintains that the mathematical formulas for PaSS and genome semi-distance must be recited in the claim, but this is unnecessary.

First of all, the formulas at issue need not be recited in the claims because they concern how to practice determine. The claims define the legal limits of the invention, the specification details *how* the invention is to be *practiced*. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973).

Secondly, even assuming the formulas at issue define the terms PaSS and genome semi-distance, they need not be recited in the claims because they are set forth in the specification. While *limitations* from the specification cannot be read into the claims, words in the specification are

properly used during prosecution as an aid in *interpret existing claim limitations*. This distinction is examined in the decision *In re Donaldson Co. Inc.*, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994).

The Commissioner confuses [1] impermissibly imputing limitations from the specification with [2] properly referring to the specification to determine the meaning of a particular word or phrase recited in a claim.

Since the definition intended for the claim terminology is set forth in the specification, it must be used in order to examine the claims.

When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art.

In re Zletz, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Moreover, claim terms need not be "conventional" in the art, since a patent applicant is entitled to be his own lexicographer. *In re Castaing*, 166 USPQ 550 (CCPA 1970). It must be remembered that applicants have the exclusive prerogative to define the claims. *In re Pilkington*, 162 USPQ 145, 148 (CCPA 1969).

Claims 1-7 were rejected for allegedly lacking patentability under 35 USC 103(a) based on Rolleke in view of Pena, further in view of Pleissner. Reconsideration is requested in view of the changes in the claims effected, hereby, and the following remarks.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of

[the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002). When conducting an obviousness analysis, "all limitations of a claim must be considered in determining the claimed subject matter as is referred to in 35 U.S.C. 103 and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982).

The statement of rejection alleges that Rolleke fully meets claim 1 except for the feature (limitation) of random PCR and two-dimensional DGGE with subsequent mathematical analysis of the pattern of spots generated by the DNA fragments. According to the statement of rejection, it would have allegedly been obvious to one of ordinary skill in the art to modify the method of Rolleke to incorporate the random PCR method of Pena, instead of more traditional PCR technology, in order to improve the quality of the results from Rolleke's method by providing a consistently repeatable starting material with a unique pattern of DNA fragment for each organism. The aforesaid allegations are incorrect.

Rolleke also fails to teach the feature of step (e) in the present claims, i.e., that the PaSS and/or genome semi-distance(s) obtained is compared to the PaSS and/or genome semi-distance(s) recorded in a database in order to identify the organism, and this database is obtained by a method in which steps (a)-(d) are carried out with respect to known organisms under the same conditions as the steps (a)-(d) are carried out on the organism to be identified.

Rolleke further fails to teach that a standard DNA is co-migrated with the double-stranded DNA fragments as an internal reference for providing a standard point and location of the recorded position of the featuring points in relation to the featuring points of the standard DNA.

The foregoing differences between Rolleke and the present claims are neither taught nor suggested by secondary references Pena or Pleissner, taken alone or in combination.

Species identification reported by Rolleke utilizes comparison of 16S rDNAs extracted from the organism to be identified and of a reference organism. The information for identification obtainable from 16S rDNA is very limited. In contrast, in the method of the invention the whole genome of the organism to be identified may be basis of species identification but not limited to a specific NDA such as 16S rDNA and this means that the quantity of the information underlying in the method is quite larger than those utilizing in the method taught by Rolleke and resulting in accomplishment of species identification much easier.

Use of Random PCR makes it possible to utilize the whole genome for species identification in this invention but Pena fails to teach the random PCR for species identification.

However, in the method of Rolleke, the target DNA to be amplified is 16S rDNA and nobody assume that in such a method, use of the random PCR instead of traditional PCR will provide an improved quality of the results from Rolleke's method. It would be suspected that the use of the random PCR instead of traditional PCR in the method of Rolleke results in not only amplification of 16S rDNA but also amplification of DNAs other than 16S rDNA since the primers specific for 16S rDNA in the traditional PCR are capable to attach to the DNAs other than 16S rDNA in random

PCR because of lower annealing temperature of random PCR and further suspected that it would be hard to identify species from a gel image obtained electrophoresis of a mixture of the amplified 16S rDNA and DNAs other than 16S Rdna.

In contrast, in the method of the presently claimed invention, combination of random PCR and RGGE or DGGE with use of PaSS makes it possible to use a gel image obtained electrophoresis for species identification.

As explained, above, all of the features (limitations) in the claims are neither taught nor suggested by the cited references and, so, the rejection of record under §103(a) cannot be maintained. *Royka, supra*. Since "the cited references do not support each limitation of [the] claim[s]," the §103(a) rejection is "inadequate on its face," *Thrift*, 63 USPQ2d at 2008.

Moreover, the rejection under §103(a) cannot be sustained because it fails to apply the proper standards for determining obviousness under §103(a). According to the statement of rejection, it would have been obvious to modify the Rolleke method to add the step of separating the amplified DNA fragments based on size prior to DGGE allegedly because: "This additional step was routinely practiced by those skilled in the art, and would allow a more detailed analysis of the pattern of DNA fragments produced by PCR" (Office Action, page 7, 1st full ¶). First, that the step was routinely practiced merely establishes that *how* to practice the step was known, which is insufficient to show that the modification would have been obvious under §103(a). Controlling precedent has repeatedly "rejected the argument that *undirected* skill of one in the pertinent art is an adequate substitute for statutory prior art." *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) (*emphasis added*). When "the

examiner's comments regarding obviousness amount to an assertion that "one of ordinary skill in the relevant art would have been able to arrive at [the claimed] invention because he had the necessary skills to carry out the requisite process steps[,] [t]his is an inappropriate standard for obviousness." *Ex parte Levengood*, 28 USPQ2d 1300, 1301 (BPA&I 1993).

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In re Fritch, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). "That which is within the capabilities of one skilled in the art is not synonymous with obviousness [citations omitted]." *Levengood*, 28 USPQ2d at 1302.

Secondly, assuming adding the step would have, in fact, allowed "a more detailed analysis of the pattern of DNA fragments produced by PCR" does not, by itself, show that the modification would have been obvious under §103(a). When the

PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears *in the reference*.

In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (*emphasis added*). An argument by the PTO is "not prior art." 28 USPQ2d at 1957. When the claimed invention requires modification of the prior art, there is no obviousness under §103 when "[t]he prior art does not suggest . . . modification of the . . . [prior art], or provide any reason or motivation to make the modification."

In re Laskowski, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989).

The statement of rejection, further, alleges that it would have been obvious to modify the method of Rolleke to analyze the data generated "by the inclusion of additional electrophoresis step, using an algorithm to produce an objective, quantitative description of the data to allow comparisons of the DNA fragment patterns produced by a plurality of organisms. One of ordinary skill in the art *would have been motivated* to select an algorithm among those taught in the prior art *"based on experimental design and desired results"* (Office Action, page 7, first complete paragraph) (*emphasis added*). Relying "on experimental design and desired results" for the motivation necessary to establish obviousness of under § 103(a) is misplaced.

"Reliance on *per se* rules of obviousness is legally incorrect and must cease." *In re Ochiai*, 37 USPQ2d 1127, 1129 (Fed. Cir. 1995). If the prior art fails to disclose a rationale for varying parameters to be result effective, it can not have been obvious to choose the claimed parameter. *In re Antonie*, 195 USPQ 6 (CCPA 1977). Obviousness cannot be based on speculation.

The examiner should be aware that "deeming" does not discharge him from the burden of providing the requisite factual basis and establishing the requisite motivation to support the conclusion of obviousness. . . . The examiner's reference to unidentified phantom prior art techniques . . . falls short of the mark.

Ex parte Stern, 13 USPQ2d 1379, 1382 (BPA&I 1989).

Whether the changes form the prior art are "minor", as . . . [patent challenger] argues, the changes must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the . . . [claimed] method and device.

Northern Telecom, Inc. v. Datapoint Corporation, 15 USPQ2d 1321, 1324 (Fed. Cir. 1990).

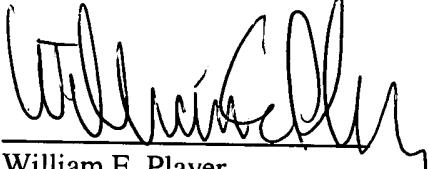
Differences between the claimed structure and the prior art structure do not amount to "an obvious design choice," when "the different structures . . . achieve different purposes." *In re Gal*, 25 USPQ2d 1076, 1078 (Fed. Cir. 1992). Where the *optimization* of a claim variable was not recognized in the art as effecting the claimed result, the result is unobvious. *In re Antonie*, 195 USPQ 6, 8 (CCPA 1977). That a difference with the prior art amounts to an alleged "optimal condition . . . is not a substitute for some teaching or suggestion supporting an obviousness rejection." *Rijckaert*, 28 USPQ2d at 1957.

In the event the rejection under §103(a) is maintained, Applicants respectfully request that the examiner support the rejection as required in accordance with In accordance with 37 CFR
Favorable action is requested.

Respectfully submitted,

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